



Garlic Oil Final Work Plan

Registration Review Case 4007

Docket Number: EPA-HQ-OPP-2009-0113

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Approved By:

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Date: _____

I. INTRODUCTION

This document is EPA's Final Work Plan for Garlic Oil. The work plan includes the expected registration review time lines. The final work plan is intended to address any public comments received concerning the Preliminary Work Plan in the Summary Document, which was posted in the Garlic Oil registration review docket (EPA-HQ-OPP-2009-0113) concerning the initial docket postings. The Summary Document provided information on what EPA knows about the pesticide and what additional risk analyses and data or information the Agency believes are needed to make a registration review decision.

The Food Quality Protection Act (FQPA) of 1996 mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States must generally be registered by EPA, based on scientific data showing that they will not cause unreasonable risks to human health (including occupational and non occupational exposures), or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can continue to be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

In 2006, the Agency implemented the Registration Review program pursuant to FIFRA Section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

The EPA first registered a product containing garlic oil in 1983. There are 11 products registered with the Agency containing garlic, garlic oil, and garlic powder. The labels for these products list the active ingredient as Garlic Oil, Garlic Juice, Garlic Water, or Garlic. The Agency considers all such variations of garlic or garlic oil as falling under the PC Code 128827 and Registry Number 8000-78-0. Further references herein are to garlic oil or garlic. Of the 11 registered products containing garlic oil as an active ingredient, two products are registered as insect repellents for agricultural use. The remaining products are registered for use as animal and insect repellents. Two of the 11 products contain garlic oil as the only active ingredient. The other products contain additional minimal risk products such as capsaicin, and putrescent whole egg solids as active ingredients along with garlic. All products are water-based compounds with extract of garlic or garlic powder.

As a biochemical active ingredient, garlic oil is used as a repellent for the control of insects, mites, birds, deer, rabbits and squirrels and is registered for use on terrestrial food and feed such as vegetables, fruits nuts and grains. Garlic oil is also registered for use on terrestrial non-food crops such as ornamental plants and shrubs.

II. RESPONSES TO COMMENTS

During the 60 day comment period that closed on May 26, 2009, the Agency received no comments.

III. RISK ASSESSMENT AND DATA NEEDS

Product Chemistry Assessment

All product chemistry data requirements for garlic oil have been satisfied. Assessment of these data show that they continue to meet the standard for registration under FIFRA, as amended by the FQPA. No further product chemistry data are required. For currently registered label uses of garlic oil, please refer to the Garlic Oil Summary document posted in the initial docket (EPA-HQ-OPP-2009-0113) for a more detailed discussion.

Human Health Risk Assessment

Based on the available data and information, the Agency does not foresee the need for new data or for a new human health risk assessment. All data requirements per 40 CFR 158.2050 have been fulfilled for garlic oil. Please refer to the Garlic Oil Summary document posted in the initial docket (EPA-HQ-OPP-2009-0113) for a more detailed discussion.

Environmental Fate and Ecological Risk Assessment

1. Effects on Nontarget Organisms

All nontarget toxicity data requirements for garlic oil have been fulfilled and meet the standard for registration required under FIFRA, as amended by FQPA. Based on the available information for garlic oil, the Agency does not foresee the need for additional ecotoxicity data or a new risk assessment. Please refer to the Garlic Oil Summary document posted in the initial docket (EPA-HQ-OPP-2009-0113) for a more detailed discussion.

2. Endangered Species Risk Assessment

The Agency has not completed an endangered species risk assessment at this time. An endangered species assessment will be conducted prior to the issuance of the Proposed Final Decision.

IV. ESTIMATED TIMELINE

Activities	Estimated Month/Year
Open Public Comment Period for Garlic Docket	March 2009
Close Public Comment Period	May 2009
Phase 2: Case Development	
Develop Final Work Plan (FWP)	September 2009
Complete Endangered Species Assessment	October 2009
Phase 3: Registration Review Decision	
Open Public Comment Period for Proposed Registration Review Decision	February 2010
Close Public Comment Period	April 2010
Final Decision and Begin Post-Decision Follow-up	September 2010
*Estimated Total (years)	1 year 5 months

* EPA has created the following estimated timeline for completion of the garlic registration review case. This schedule is subject to revision should unforeseen issues arise during the registration review process.

V. NEXT STEPS

As mentioned in the Risk Assessment and Data Needs section above, an Endangered Species assessment is ongoing and will be complete in advance of the announcement of a Proposed Registration Review Decision.